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August 31, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room1061
Rockville, MD 20852

Via FedEx

Re: 2nd Request for a variance for Fluoroscan InSight Mini C-Arm Fluoroscopic Imaging System.

Dear Sir/Madam,

The purpose of this letter is to request a variance for the Fluoroscan Insight Mini C-Arm Fluoroscopic Imaging System. As per the Agency's request two (2) additional copies of this request are enclosed.

The following information is being provided as outlined in 21 CFR 1010.4(b), "Applications for variances."

i) **Description of Product:** The Fluoroscan InSight is a Mini C-Arm Fluoroscopic Imaging System designed to provide physicians with general fluoroscopic visualization of a patient, including but not limited to, surgical orthopedic and podiatry use, critical and emergency care procedures, and light anatomy imaging situations. See Attachment A for a detailed description and comparison to it's predicate, the Encore Premier for which a variance (00V-1261) has been granted.

ii) **Explanation of How Compliance Would Restrict Intended Use:** Compliance with current limitations of permissible S.S.D. such as those imposed on large, mobile, image intensified fluoroscopes would restrict intended use. Doing so would require that the available free space of the InSight Mini C-Arm be reduced, or the size of the C-arm be increased. Reducing the available free space would severely limit the utility of the min-c-arm for its intended purpose. At the same time, increasing the size of the c-arm to preserve the free space would compromise the safety aspect of the min-c-arm by requiring the use of a larger, more powerful x-ray tube.

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InSight Mini C-Arm be reduced, or the size of the C-arm be increased. Reducing the available free space would severely limit the utility of the min-c-arm for its intended purpose. At the same time, increasing the size of the c-arm to preserve the free space would compromise the safety aspect of the min-c-arm by requiring the use of a larger, more powerful x-ray tube.

iii) **Proposed Deviation from Requirements:** Hologic's proposed deviation from the requirement is to reduce the minimum source-skin distance to nine (9) centimeters. This is identical to that of the existing products currently manufactured under variance number 00V-1261 by our company.

iv) **Advantages Derived from Requirements:** The limitation of the InSight's x-ray output and the geometry of its c-arm are interrelated and have been balance to optimize the system's utility and to provide a high level of safety for both the patient and the system operator. On one side of the equation is the need to keep the overall S.I.D. as small as possible so smaller x-ray sources producing conservative levels of x-rays can be used. On the other side of the equation is the need for a relatively large free space and C-arm depth to accommodate the anatomy being imaged along with other necessary objects and implements. The primary application for the InSight Mini-C-Arm is the surgical and non-surgical examination of the extremity body parts. These body parts not only vary with the size of the patient, but may also include or are impeded by traction devices, internal and/or external fixation devices, casts splint materials introduced before or during a procedure. While being imaged by a mini c-arm fluoroscope, an extremity can easily take up much more space than the actual body part itself. In this context, one can see why mini c-arms with large free spaces are preferable to mini c-arms with small ones.

v) **Alternate Means of Radiation Protection:** Suitable means for radiation safety and protection will be provided by constraints on the design and by supplemental information and labeling provided to users. The design constraints are similar to those for the Encore Premier, (See Attachment A).

vi) **Time Limit of Variance**: Hologic requests that this variance be in effect for a period of five (5) years or until the effective date of any new applicable regulations concerning small format c-arm x-ray systems, whichever comes first.

vii) **Prototype and Experimental Equipment Location**: The Fluoroscan InSight Mini C-arm Fluoroscopic Imaging System was cleared by FDA (K051025) on May 13, 2005. All equipment will be located at our manufacturing facility. See letterhead for address.

viii) **Other Information Required by CDRH:** A copy of the Device Information submitted to FDA in the Special 510(k) Premarket Notification for Fluoroscan

x) **Reserved.**

xi) **Electronic Products Used in Clinical Investigation Involving Human Subjects:** InSight was not used in clinical investigations involving human subjects.

I hope you will find the information in this request sufficient to issue a variance letter for the Insight system. If you require any other information, please contact me directly at 781-999-7313 or by email arandall@hologic.com.

Sincerely,

Anastasia C. Randall
Senior Regulatory Affairs Specialist
Hologic, Inc.

Enclosures